

### Remarks

Claims 18, 19, 22-32, 34-47, 49-60, 62-72, and 74-92 will be pending upon entry of this amendment. Claims 10-12, 14-17, 20-21, 33, 48, 61, 73, and 86-92 have been canceled without prejudice or disclaimer.

Claims 18 and 19 have been amended so as to refer to the elected polynucleotide. No new matter has been added to the claims by way of amendment. Claims 18-19 have been withdrawn by the Examiner as directed to a nonelected group.

Claims 22, 23, 34, 35, 49, 62, 74, and 79 have been amended to recite "consisting of" instead of "comprising". Claims 25, 40, 53, 65, 75, 82, and 89 have been amended to recite "is fused to" instead of "comprises". Claims 49-53 have been amended to specify that the recited polynucleotide encodes "a portion of SEQ ID NO:66". Claims 41, 52, 53, 65, 67, 68, 70, and 72 have been amended to correct references to other claim numbers, which were previously erroneous due to typographical errors. These amendments more clearly specify that which Applicants regard as the invention and do not add new matter.

Claim 62 has also been amended to recite that the isolated polynucleotide hybridizes over its full length with either SEQ ID NO:65 or its full complement. Support is found in the specification at page 14, lines 7-11. Thus, the amendment does not add new matter.

The title has been amended to be more descriptive of the claimed subject matter, as requested by the Examiner. The amendment is supported *inter alia* by Table 1. Thus, no new matter is introduced by this amendment.

### I. The Restriction Requirement

Applicants' election with traversal of the claims of Group I as directed to SEQ ID NOS:65 and 66 has been made final. Applicants note, however, that claims 18 and 19 are directed to methods of detecting *Streptococcus*, formerly classified by the Examiner as Group V. Since the polynucleotides of Group I and the methods of Group V related as between a product and a process for using the product, and the process claims include all the limitations of the product, the Examiner in any case would be obligated to rejoin the method claims if the elected product claims are found allowable. In light of the decisions in *In re Ochiai*, 71 F.3d 1565, 37 USPQ2d 1127 (Fed. Cir. 1995) and *In re Brouwer*, 77 F.3d 422, 37 USPQ 2d 1663 (Fed. Cir. 1996), a notice was published in the Official Gazette which set

forth new guidelines for the treatment of product and process claims. See 1184 OG 86 (March 26, 1996). Specifically, the notice states that "in the case of an elected product claim, rejoinder will be permitted when a product claim is found allowable and the withdrawn process claim depends from or otherwise includes all the limitations of an allowed product claim." *Id.* Accordingly, Applicants respectfully request that if any of the claims of Group I are found allowable, the process claims of Group V be rejoined and examined for patentability.

## II. The Written Description Rejection

Claims 22-32, 34-47, 49-60, 62-72, and 74-92 are rejected as allegedly lacking written description. The rejection is respectfully traversed.

Initially, it is noted that the concerns regarding claim 2 which are expressed in Paper No. 13 at page 5, line 15, through page 6, line 6 have been obviated by the cancelation of claim 2.

The Examiner is concerned that the claims as previously presented, due to use of the word "comprising" in several of the claims, would read on undisclosed flanking sequences or sequences of undisclosed genes. Applicants disagree. However, the claims have been amended to recite "consisting of" with respect to the claimed sequences, which Applicants believe would alleviate the Examiner's concern and overcome the rejection. Thus, the withdrawal of this rejection is respectfully requested.

## III. The Enablement Rejections

### A. Claims 22-32, 34-47, 49-60, 62-72, and 74-92

Claims 22-32, 34-47, 49-60, 62-72, and 74-92 are rejected as allegedly lacking enablement. This rejection is respectfully traversed.

The Examiner's concerns regarding enablement are based in part on the same objections expressed in the written description rejection, *i.e.*, that the claims capture undescribed sequences. For example, the Examiner states:

Applicant's specification (page 5, lines 17-37) sets forth that the polynucleotide of the invention can be used diagnostically. However, such a detection is limited to consisting of SEQ ID NO:65 or specific fragments thereof, since the addition of an indefinite number of nucleotides 3' and 5' to SEQ ID NO:65 would unpredictably effect the ability to use SEQ ID NO:65 in a well established manner. Applicant's have not demonstrated that large sequences comprising SEQ ID NO:65 have this ability.

Paper No. 13 at page 8, lines 3-8. Applicants maintain that the claims as amended do not recite any undescribed sequences, as discussed above. Furthermore, the claimed polynucleotides can be used not only for the detection of *Streptococci*, but also as antigens for vaccines. For example, the specification at page 9 states that the disclosed nucleic acid sequences were selected because they encode potentially immunogenic peptides. The specification then goes on to describe the selection of the immunogenic polypeptides at page 9, last paragraph, through page 11, first whole paragraph. The sequences were identified by analysis which included use of an algorithm, the presence of certain signal sequences, the presence of a consensus sequence for lipoprotein cleavage, and the presence of a consensus sequence for surface anchoring in gram-positive bacteria. Thus, not only the polynucleotide of SEQ ID NO:65 and fragments thereof, but also the claimed variant sequences are enabled by the disclosure, because the variants can be used as immunogens in a vaccine in the same manner as SEQ ID NO:65.

Moreover, the Examiner is concerned by the absence of typical start and stop codons in SEQ ID NO: 65, which would denote a full length open reading frame. The specification teaches clearly that "[t]he selected ORFs do not consist of complete ORFs." Specification at page 9, line 22. The specification explains further in the same paragraph that portions of the complete ORFs have been deliberately omitted in order to simplify production of the recombinant protein, for example, by removing highly hydrophobic sequences. Thus, the selected ORFs are not complete because they have been modified to improve their use as antigens. Furthermore, the specification discloses that a more complete listing of the *S. pneumoniae* genome can be found in copending application Ser. No. 60/029,960, filed October 31, 1996. Specification at page 9, lines 16-19. The ordinary skilled artisan would have no difficulty identifying the complete ORF in the copending application based on the disclosure of SEQ ID NO:65 in the instant application. Copending application Ser. No. 60/029,960 has been incorporated by reference in the instant specification. See specification at page 9, lines 18-19. The complete ORF is disclosed in Table 2 of Ser. No. 60/029,960 as ORF5 of Contig ID No. 94.

Thus, Applicants assert that the claims are enabled as to their entire scope and respectfully request the withdrawal of this rejection.

B. Claims 65, 66, 68, 69, 71, and 72

These claims are rejected as lacking enablement because they recite polynucleotides complementary to SEQ ID NO:65 which do not encode the polypeptide of SEQ ID NO:66. The appropriate claims have been amended to no longer recite polynucleotides complementary to SEQ ID NO:65. Therefore, as the rejection pertains to the amended claims, Applicants respectfully traverse the rejection and request its withdrawal.

The Indefiniteness Rejection

Claims 41 and 86-92 are rejected as indefinite. As the rejection pertains to the amended claims, Applicants respectfully traverse the rejection and request its withdrawal.

The dependency of claim 41 has been corrected.

Claim 86 has been amended to recite "consisting of a portion of SEQ ID NO:65 or the full complement thereof, said portion consisting of at least . . . ." Applicants believe the ambiguity perceived by the Examiner has been removed by the amendment.

Rejections Under 35 U.S.C. 102

A. 35 U.S.C. 102(b)

Claim 62 is rejected as allegedly anticipated by Birkett et al. or Boehringer Mannheim 1991 Catalog or Stratagene 1991 Catalog. The cited references allegedly inherently disclose six consecutive nucleotides that would hybridize under stringent conditions with SEQ ID NO:65 or its complement. The rejection is respectfully traversed.

Claim 62 has been amended to recite that the isolated polynucleotide hybridizes with the full length of either SEQ ID NO:65 or its full complement. Thus, as amended, the claim is not anticipated by the cited references. Withdrawal of the rejection is respectfully requested.

B. 35 U.S.C. 102(e)

Claims 34, 49, 62, 65, 66, 67, 68, 69, 70, 71, and 86-92 are rejected as allegedly anticipated by Bergeron et al., who teach a fragment of *S. pneumoniae* genomic DNA which has 106 consecutive nucleic acids in common with SEQ ID NO:65. This rejection is respectfully traversed.

Bergeron et al. disclose merely a genomic DNA fragment with no reference to any open reading frame and without any disclosure or prediction of a possible encoded amino

acid sequence. Bergeron et al. provide no evidence or teaching that the disclosed sequence encodes a polypeptide or any portion thereof. Therefore, Bergeron et al. do not disclose all the elements of claims 34 (encodes an epitope) or 49 (encodes at least 9 consecutive amino acids). Claim 62 has been amended to require hybridization over the full length of either SEQ ID NO:65 or its full complement. Claims 86-92 have been canceled.

Thus, Bergeron et al. does not anticipate any of the present claims. Withdrawal of the rejection is respectfully requested.

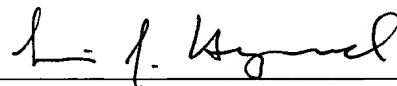
### Conclusion

In view of the foregoing remarks, Applicants believe that this application is now in condition for allowance. An early notice to that effect is urged. The Examiner is invited to call the undersigned at the phone number provided below if any further action by Applicant would expedite the examination of this application.

Finally, if there are any fees due in connection with the filing of this paper, please charge the fees to our Deposit Account No. 08-3425. If a fee is required for an extension of time under 37 C.F.R. § 1.136 not accounted for above, such an extension is requested and the fee should also be charged to our Deposit Account.

Respectfully submitted,

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